



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/550,939 | 09/28/2005 | Ian Hughes | PB60179USw | 4596 |
| 23347 | 7590 | 07/09/2008 | EXAMINER | |
| GLAXOSMITHKLINE | | | HOBBS, MICHAEL L | |
| CORPORATE INTELLECTUAL PROPERTY, MAI B482 | | | | |
| FIVE MOORE DR., PO BOX 13398 | | | ART UNIT | PAPER NUMBER |
| RESEARCH TRIANGLE PARK, NC 27709-3398 | | | 1797 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 07/09/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/550,939 | HUGHES ET AL. | |
| | Examiner | Art Unit | |
| | MICHAEL HOBBS | 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 September 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 28 September 2005 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>09/28/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Applicant is advised that should claim 2 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1, 4, 11, 19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. On line 7 of claim 1 and on line 2 of claim 4, the applicant claims a "means [is] adapted to vary the physical condition within in or of the channel structure" with no explanation of the means. One of ordinary skill in the art would not be able to determine

what the "means" to "vary the physical conditions" within the channel is and this renders the claims indefinite.

6. The term "predetermined objective" in claim 11 is a relative term which renders the claim indefinite. The term "predetermined objective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of the term "predetermined objective" renders the parameter "predetermined property" as also indefinite since there is no explanation of how the "objective" couples with the product produced by the control mechanism to generate the property that satisfies an unknown criterion. Further, one of ordinary skill in the art would not be able to ascertain the goals which determine the end of the reaction and this term renders the claim indefinite.

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 19 provides for the use of a method of screening chemical compounds and claim 23 provides for the use of a method of optimizing a predetermined property, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 19 and 23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

9. Appropriate corrective action is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Parce et al. (US 6,046,056).

12. Parce discloses a high-throughput screening assay system for micro-scale fluidic devices. For claim 1, Parce discloses a micro-fluidic system that is a closed loop system (Fig. 6c) that can be operated on a continuous basis (col. 8 lines 10-12) and is fully capable of being automated. Sensors are used within the device to detect signals from the stream such as chromophoric or fluorescent signals (col. 8 lines 26-28, 61-62). The conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8

lines 62-63). The device is connected to computer (col. 22 lines 4-8) which controls the fluid flow through the chambers and analyzes the data (“receive[s] the sensor signal”) from the screening and is fully capable of adjusting the conditions within the channel based on this data.

13. With regards to claims 2 and 3, the sensor sends a signal to the computer as discussed above relating to the fluorescent signal generated from the target molecule (col. 8 lines 26-28). With regards to claim 4, the physical condition within the channel such as fluid flow can be controlled by the computer (col. 22 lines 4-8). Furthermore, the conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8 lines 62-63) and for claim 5 Parce teaches using micro-pipettors for introducing test compounds or reagents to the device (col. 22 lines 25-26). With regards to claims 6 and 7, Parce discloses a buffer system (720) that fills the plates on a conveyor system (col. 21 lines 61-64) which the computer is fully capable of operating and the test compounds are within a multi-well plate or array (col. 22 lines 28-30).

14. For claim 8, as stated above, the computer is fully capable of controlling the buffer system and the additions of test compounds from the multi-well plates will vary the conditions within the channel. Regarding claim 9, Parce teaches at least two inlets with one inlet “downstream” from another inlet (Fig. 6c). For claim 10, the computer of Parce is fully capable of running the system without intermediate instruction from an operator. With regards to claim 11, the computer of Parce is fully capable of running the reaction within the channel until the “physical property” satisfies a “predetermined

objective". For claim 12, Parce discloses that the "predetermined property" is the fluorescence of the target solutions as was discussed above. With regards to claim 13, the computer of Parce is fully capable of not controlling conditions within the channel (i.e. the computer is turned off).

15. With regards to claim 14, Parce discloses a chemical property such as a colormetric or fluorometric response from the device (col. 10 lines 42-45). Parce discloses for claim 15 that the cellular activity is monitored by the device (col. 4 lines 65-67). For claim 16, Parce teaches that the conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8 lines 62-63). With regards to claim 17, Parce also discloses controlling the flow rate or geometry of the channel through fabricated fluid direction devices such as pumps and valves (col. 18 lines 16-22). For claim 18, the computer is an integrated part of the system (col. 22 lines 4-8).

16. With regards to claim 19, Parce discloses using the system as discussed above for claim 1 (col. 2 lines 48-65) for the high-throughput micro-fluidic system.

17. For claim 20, Parce discloses using a micro-well plate or array with test compounds (col. 22 lines 28-32) with a computer to control the device where each well has a different test compound (col. 2 lines 48-67) through micro-fluidic channels. For claim 21, Parce teaches that the test compounds are identified or categorized (col. 5 lines 17-21) as effective pharmacological agents for the treatment of disease.

18. Therefore, Parce meets the limitations of claims 1-21.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (US 6,046,056).

23. Parce discloses using the system as discussed above for claim 1(col. 2 lines 48-65) for the high-throughput micro-fluidic system. With regards to claims 22 and 23, Parce does not specifically teach that the computer operates the system "heuristically" (learns) or that the "predetermined property" is optimized. However, the use of a computer or algorithm that adjusts the parameters based on feed back from the system is within the skills of one of ordinary skill in the art. Further, Parce implies that the computer optimizes the system for the reaction within the micro-channels where the monitored property is optimized for the target solution being screened by the devices. Therefore, it would be obvious to one of ordinary skill in the art to employ an "intelligent" computer and optimize the reaction based on the teachings of Parce in order to determine which of the samples are contain the most effective pharmacological agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M.H./
MLH